

George M. Haley – UT 1302
David R. Parkinson – UT 8268
HOLME ROBERTS & OWEN LLP
299 South Main Street, Suite 1800
Salt Lake City, UT 84111
(801) 521-5800

Charles W. Douglas (*pro hac vice*)
Richard F. O'Malley, Jr. (*pro hac vice*)
Lisa A. Schneider (*pro hac vice*)
Neil H. Wyland (*pro hac vice*)
Todd L. Krause (*pro hac vice*)
Sidley Austin LLP
One South Dearborn Street
Chicago, IL 60603
(312) 853-7000

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION**

BRIGHAM YOUNG UNIVERSITY, a Utah non-profit educational institution; and DR. DANIEL L. SIMMONS, an individual,

Plaintiffs,

VS.

Case No. 2:06CV00890 DAK
Judge Dale A. Kimball

PFIZER, INC., a Delaware corporation, G.D. SEARLE & COMPANY, a Delaware corporation, G.D. SEARLE LLC, a Delaware limited liability company, MONSANTO COMPANY, a Delaware corporation; and PHARMACIA CORPORATION, a Delaware corporation,

Defendants.

**DEFENDANTS PFIZER INC., G.D. SEARLE LLC, AND PHARMACIA
CORPORATION'S ANSWERS TO COMPLAINT**

NOW COME Defendants Pfizer Inc., G.D. Searle LLC ("Searle/1933 Monsanto")

(improperly captioned in Plaintiffs' Complaint by the addition of named Defendant "G.D. Searle & Company"), and Pharmacia Corporation f/k/a Monsanto Company (improperly captioned in Plaintiffs' Complaint by the addition of named Defendant "Monsanto Company"), and for their answer to Plaintiffs' Complaint state as follows:

Preliminary Statement

Plaintiffs' Complaint mischaracterizes the historic development of cyclooxygenase-2. In an effort to concoct a role for Dr. Daniel L. Simmons and Brigham Young University ("BYU") in Searle/1933 Monsanto's discovery of Celebrex, Plaintiffs' Complaint also attempts to rewrite the Research Agreement dated July 8, 1991 ("Research Agreement"), entered into by BYU and Searle/1933 Monsanto. Defendants will not address each and every one of the false and misleading statements in the Complaint in this Preliminary Statement. Suffice it to say that, despite Plaintiffs' allegations, the Research Agreement was nothing more than a short-term research grant that was mutually terminated by the agreement of the parties after it became clear that Dr. Simmons had breached the Research Agreement. BYU was fully paid under the research grant, and that grant simply does not create the obligations alleged in Plaintiffs' Complaint. For example, Plaintiffs take the position that Dr. Simmons was the first to discover cyclooxygenase-2 and that the Research Agreement somehow prevented Defendants from searching for cyclooxygenase-2 selective inhibitors. However, the idea of multiple forms of cyclooxygenase was publicly proposed by Dr. Phillip Needleman and his colleagues at least as early as 1982. Dr. Needleman and his colleagues also proposed the idea of selectively inhibiting cyclooxygenase-2 at least as early as 1989, long before meeting Dr. Simmons, and they continued to pursue the idea internally and in published papers. Nothing in the Research Agreement precluded Defendants from continuing their own cyclooxygenase-2 research. Similarly, Plaintiffs assert that the Research Agreement somehow created a fiduciary obligation on the part of Defendants. Yet, BYU is a sophisticated university with a technology transfer office, and the Research Agreement was an arms-length transaction. As a major university in

possession of a variety of patents, BYU was capable of protecting its intellectual property and contractual interests, and it begs credibility to argue otherwise. Plaintiffs also allege that Defendants improperly used materials provided to them by Dr. Simmons and that the Research Agreement required that those materials be used in only certain ways. The evidence will establish, however, that Dr. Simmons provided certain reagents without any expectation of confidentiality, that he published the sequence of cyclooxygenase-2 in chicken for the world to see, and in any event, that Celebrex was not tested using his cyclooxygenase-2 reagents. BYU and Dr. Simmons have no rights in connection with Celebrex, a drug that was first synthesized in October 1993, long after the mutual termination of the Research Agreement, and they are not entitled to any damages. To the extent the allegations of Plaintiffs' Complaint mischaracterize and misconstrue the scientific and factual background of this dispute, Defendants deny them, as addressed in more detail below.

The Complaint appears to improperly refer to confidential information pertaining to previously litigated disputes that are subject to protective orders. The Complaint also refers to confidential laboratory notebooks and other facts that were disclosed to Plaintiffs under an obligation of confidentiality. To the extent Plaintiffs' allegations pertain to documents covered by these protective orders or confidentiality obligations, they should be denied as improper.

The Complaint improperly and repetitively refers to "Monsanto" and certain improperly named defendants, including an unrelated entity, on a collective basis. Defendants have nevertheless attempted to respond to Plaintiffs' allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other

entities, Defendants are without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Defendants deny those allegations.

The Complaint improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the Complaint are vague or conclusory. The Complaint also includes terms which are undefined and which are susceptible to different meanings. Defendants have interpreted these terms in good faith and responded accordingly. Defendants' interpretations, however, may not correspond to Plaintiffs' interpretations.

In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Defendants deny each and every allegation contained in the Complaint, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes, or speculations which are contained in any averment or in the Complaint as a whole. Moreover, Defendants specifically deny any allegations contained in headings, footnotes, the Table of Contents, or unnumbered Paragraphs in the Complaint.

These comments and objections are incorporated, to the extent appropriate, into each numbered Paragraph of this Answer.

Responses to Specific Allegations in Plaintiffs' Complaint

1. On information and belief, Defendants admit that Dr. Simmons is a professor at BYU. Defendants admit that Celebrex is approved by the United States Food and Drug Administration ("FDA") as a non-steroidal anti-inflammatory drug with a mechanism of action that inhibits cyclooxygenase-2 and, at therapeutic doses, does not inhibit cyclooxygenase-2. Defendants further admit that Celebrex and Bextra have generated total sales exceeding \$20 billion. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 1 of Plaintiffs' Complaint.

2. Defendants admit that a "Research Agreement" dated July 8, 1991, was signed by Dr. Needleman and J. Bevan Ott and that a copy of the "Research Agreement" purports to be attached to the Complaint as Exhibit A. Defendants deny, however, that the allegations in Paragraph 1 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. Defendants further admit that Dr. Simmons visited Searle/1933 Monsanto in 1991. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 2 of Plaintiffs' Complaint.

3. Defendants admit that Celebrex was the first medicine to be approved by the FDA as a non-steroidal anti-inflammatory drug with a mechanism of action that inhibits cyclooxygenase-2 and at therapeutic doses, does not inhibit cyclooxygenase-2. Defendants also admit that they have obtained money from the sales of Celebrex and Bextra. Defendants further admit that Dr. Needleman and his laboratory first discovered the existence of cyclooxygenase-2 (then called inducible cyclooxygenase). Defendants lack knowledge or information sufficient to form a belief as to the allegation that "Monsanto" was the first pharmaceutical company with the

capability of systematically testing and identifying a successful cyclooxygenase-2 selective inhibitor, and therefore deny that allegation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Defendants deny each and every allegation contained in Paragraph 4 of Plaintiffs' Complaint.

5. Defendants admit that Monsanto Company and G.D. Searle & Co. entered into a tolling agreement with BYU and Dr. Simmons bearing a date of May 8, 2001, and have attempted mediation without success. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 5 of Plaintiffs' Complaint.

6. Defendants admit that Plaintiffs purport to demand a jury trial and purport to seek damages. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 6 of Plaintiffs' Complaint.

7. Upon information and belief, Defendants admit that BYU is a private not-for-profit university located in Provo, Utah. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint, and therefore deny them.

8. Upon information and belief, Defendants admit that Dr. Simmons is a professor at BYU. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 of Plaintiffs' Complaint, and therefore deny them.

9. Defendants admit that G.D. Searle LLC is a Delaware limited liability company with its principal place of business in Illinois. G.D. Searle LLC's sole member is Pharmacia &

Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation, which is a corporation existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey. Defendants admit that, during certain times, G.D. Searle LLC developed, marketed, and distributed Celebrex throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that in January of 2001, G.D. Searle & Co. was converted from a corporation to a limited liability company, G.D. Searle LLC. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 9 of Plaintiffs' Complaint.

10. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc., and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). Defendants admit that the 2000 Monsanto is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah. The 2000 Monsanto is engaged in the agricultural business and does not and has not ever developed, manufactured, marketed, sold, or distributed Celebrex. As the 2000 Monsanto does not and has not ever developed, manufactured, marketed, sold, or distributed products relevant to this litigation, Defendants state, therefore, that the 2000

Monsanto is not a proper party in this matter. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Defendants admit that Pharmacia Corporation is a corporation existing under the laws of the State of Delaware with its principal place of business in New Jersey. Defendants admit that, during certain times, Pharmacia Corporation marketed Celebrex throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that Pharmacia Corporation is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 11 of Plaintiffs' Complaint.

12. Defendants admit that Pfizer Inc. is a Delaware corporation with its principal place of business in the State of New York. Defendants admit that, during certain times, Pfizer Inc. marketed and co-promoted Celebrex throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that Pfizer Inc. is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint.

13. Defendants respond to the factual assertions in each of the following Subparagraphs of Paragraph 13 of Plaintiffs' Complaint as follows:

- (1) Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware and that in 1985, G.D.

Searle & Co. became a wholly owned subsidiary of 1933 Monsanto. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 13(1) of Plaintiffs' Complaint.

- (2) Defendants admit that on March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc., and 1933 Monsanto changed its name to Pharmacia Corporation; that on February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware; and that on March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 13(2) of Plaintiffs' Complaint.
- (3) Defendants admit that in January of 2001, G.D. Searle & Co. was converted from a corporation to a limited liability company, G.D. Searle LLC. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 13(3) of Plaintiffs' Complaint.
- (4) Defendants admit that on March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc., and 1933 Monsanto changed its name to Pharmacia Corporation; that on February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware; and that on March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 13(4) of Plaintiffs' Complaint.

- (5) Defendants admit that in April 2003, Pharmacia Corporation and Pfizer Inc. merged and that G.D. Searle LLC is presently a wholly owned third-tier subsidiary of Pharmacia Corporation, which in turn is a wholly-owned subsidiary of Pfizer Inc. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 13(5) of Plaintiffs' Complaint.

To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 13 of Plaintiffs' Complaint.

14. Defendants state that the allegations of Paragraph 14 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 14 of Plaintiffs' Complaint, and specifically note that the Complaint does not properly state an action showing liability by any of the Defendants.

15. Defendants state that the allegations of Paragraph 15 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 15 of Plaintiffs' Complaint, and specifically note that the Complaint does not properly state an action showing liability by any of the Defendants.

16. Defendants state that the allegations of Paragraph 16 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 16 of Plaintiffs' Complaint.

17. Defendants admit that Pfizer Inc. is a Delaware corporation, G.D. Searle LLC is a Delaware limited liability company, and Pharmacia Corporation is Delaware corporation and that

Pfizer Inc., G.D. Searle LLC, and Pharmacia Corporation have their principal places of business outside of the State of Utah. Upon information and belief, Defendants admit that BYU and Dr. Simmons are both residents of the State of Utah. Defendants further admit that Plaintiffs purport to assert that jurisdiction in this Court is proper under 28 U.S.C. § 1332(a) as alleged in Paragraph 17, and aver that they do not contest that jurisdiction exists solely for the purpose of this action. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. On information and belief, Defendants admit that Plaintiffs purport to seek more than \$75,000, exclusive of interest and costs. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Defendants admit that Plaintiffs purport to assert an action for correction of inventorship under 35 U.S.C. § 256 as alleged in Paragraphs 213 through 219, and aver that they do not contest subject matter jurisdiction under 28 U.S.C. § 1331. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 19 of Plaintiffs' Complaint.

20. Defendants admit that Plaintiffs purport to assert venue is proper in this Court under 28 U.S.C. § 1391(b) as alleged in Paragraph 20 and that certain alleged events occurred within the State of Utah. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 20 of Plaintiffs' Complaint.

21. Defendants admit that Plaintiffs purport to assert that this Court has personal jurisdiction over Defendants. Defendants aver that they do not contest that this Court has

personal jurisdiction over Pfizer Inc., G.D. Searle LLC, and Pharmacia Corporation solely for the purpose of this action.

22. Defendants deny each and every allegation contained in Paragraph 22 of the Complaint.

23. Defendants admit that one or more witness who are residents of the State of Utah may testify concerning this litigation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 23 of Plaintiffs' Complaint.

24. Defendants object to the use of the term "NSAIDs" and the use of the word "similar" in Paragraph 24 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that aspirin has been used for the treatment of inflammation, pain, and fever. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Defendants object to the use of the term "NSAIDs" and the use of the word "key" in Paragraph 25 of Plaintiffs' Complaint as vague and ambiguous. Defendants deny each and every allegation contained in Paragraph 25 of Plaintiffs' Complaint.

26. Defendants object to the use of the term "NSAIDs" in Paragraph 26 of Plaintiffs' Complaint as vague and ambiguous. Defendants deny each and every allegation contained in Paragraph 26 of Plaintiffs' Complaint.

27. Defendants object to the use of the term "NSAIDs" in Paragraph 27 of Plaintiffs' Complaint as vague and ambiguous. Defendants deny each and every allegation contained in Paragraph 27 of Plaintiffs' Complaint.

28. Defendants object to the use of the term "NSAIDs" and the word "discovered" in Paragraph 28 of Plaintiffs' Complaint as vague and ambiguous. Upon information and belief, Defendants admit that ibuprofen was approved by the FDA for marketing, sale, and use in the United States as Motrin in 1974 and as Advil in 1984; naproxen was approved by the FDA for marketing, sale, and use in the United States as Naprosyn in 1976 and Aleve in 1994; sulindac was approved by the FDA for marketing, sale, and use in the United States as Clinoril in 1978; diclofenac was approved by the FDA for marketing, sale, and use in the United States as Voltaren in 1988; ketoprofen was approved by the FDA for marketing, sale, and use in the United States as Orudis in 1986; piroxicam was approved by the FDA for marketing, sale, and use in the United States as Feldene in 1982; indomethacin was approved by the FDA for marketing, sale, and use in the United States as Indocin in 1965; and meclofenamate sodium was approved by the FDA for marketing, sale, and use in the United States as Meclomen in 1980. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 28 of Plaintiffs' Complaint.

29. Defendants object to the use of the term "NSAID" in Paragraph 29 of Plaintiffs' Complaint as vague and ambiguous. Defendants deny each and every allegation contained in Paragraph 29 of Plaintiffs' Complaint.

30. Defendants object to the use of the term "NSAIDs" in Paragraph 30 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that after 1950, drug companies have made the following synthetic, anti-inflammatory steroids: prednisolone, prednisone, betamethasone, and dexamethasone. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Defendants deny each and every allegation contained in Paragraph 31 of Plaintiffs' Complaint.

32. Defendants object to the use of the term "NSAIDs" in Paragraph 32 of Plaintiffs' Complaint as vague and ambiguous. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 32 of Plaintiffs' Complaint regarding unidentified "drug researchers," and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Defendants deny each and every allegation contained in Paragraph 33 of Plaintiffs' Complaint.

34. Defendants admit that Dr. Needleman's laboratory proposed in publications and other writings: (1) the possible existence of multiple cyclooxygenase "pools," (2) the existence of multiple mRNAs generated from the same cyclooxygenase gene, and (3) the existence of multiple cyclooxygenase genes. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Defendants deny each and every allegation contained in Paragraph 35 of Plaintiffs' Complaint.

36. Defendants admit that Searle/1933 Monsanto hired Dr. Needleman from Washington University in St. Louis in 1989. Defendants further admit that, prior to his departure from Washington University, Dr. Needleman and his laboratory were looking for a new and novel treatment for inflammation and pain and that this work continued when Dr. Needleman joined Searle/1933 Monsanto. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 36 of Plaintiffs' Complaint.

37. Defendants object to the use of the terms "NSAID-like compound" and "NSAID(s)" in Paragraph 37 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that, before the Research Agreement was executed, Searle/1933 Monsanto was testing chemicals to identify a new and novel treatment for inflammation and pain. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 37 of Plaintiffs' Complaint.

38. Defendants deny each and every allegation contained in Paragraph 38 of Plaintiffs' Complaint.

39. On information and belief, defendants admit that the focus of Dr. Simmons' work while at Harvard was cancer. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 39 of Plaintiffs' Complaint, and therefore deny them.

40. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 40 of Plaintiffs' Complaint, and therefore deny them.

41. Defendants object to the use of the word "identified" in Paragraph 41 of Plaintiffs' Complaint as vague and ambiguous. On information and belief, defendants admit that Dr. Simmons came to BYU in 1989. Defendants deny that only one cyclooxygenase had been identified at the time Dr. Simmons and Weilin Xie purportedly identified the nucleic acid sequence for CEF 147. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 41 of Plaintiffs' Complaint, and therefore deny them.

42. Defendants admit that Dr. Simmons alleged in a published article (Weilin Xie *et al.*, *Expression of a Mitogen-Responsive Gene Encoding Prostaglandin Synthase Is Regulated by mRNA Splicing*, 88 Proc. Nat'l Acad. Sci. 2692 (1991)) that CEF 147 encoded a cyclooxygenase enzyme that shared 59% amino acid identity with a certain sheep cyclooxygenase enzyme isolated from sheep seminal vesicle cells. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 42 of Plaintiffs' Complaint, and therefore deny them.

43. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 43 of Plaintiffs' Complaint, and therefore deny them.

44. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 44 of Plaintiffs' Complaint, and therefore deny them.

45. Defendants admit that the article, Weilin Xie *et al.*, *Expression of a Mitogen-Responsive Gene Encoding Prostaglandin Synthase Is Regulated by mRNA Splicing*, 88 Proc. Nat'l Acad. Sci. 2692 (1991), was published, on information and belief, in 1991 and that this article does not include the nucleic acid sequence of mouse cyclooxygenase-2. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint, and therefore deny them.

46. Defendants admit that in February of 1991, Dr. Barry Haymore visited BYU to present a seminar on a subject unrelated to cyclooxygenase and that one of his responsibilities was to scout for new scientific developments that might be of benefit to Searle/1933 Monsanto.

Defendants further admit that Dr. Simmons met with Dr. Haymore and told him that he had cloned a chicken nucleic acid sequence. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. Defendants deny each and every allegation contained in Paragraph 47 of Plaintiffs' Complaint.

48. Defendants admit that Dr. Simmons agreed to give a seminar at Searle/1933 Monsanto. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 48 concerning whether Dr. Simmons forwarded materials to Searle/1933 Monsanto or what would have motivated him to do so. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 48 of Plaintiffs' Complaint.

49. Defendants admit that on April 5, 1991, Dr. Simmons made a presentation at Searle/1933 Monsanto regarding his cloning efforts and that Dr. Simmons met with Dr. Needleman. Defendants further admit that Dr. Simmons presented Searle/1933 Monsanto with a written proposal bearing a date of April 5, 1991. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Defendants deny each and every allegation contained in Paragraph 50 of Plaintiffs' Complaint.

51. Defendants admit that Dr. Simmons provided a written research proposal to Defendants bearing a date of April 5, 1991, but Defendants deny that the allegations in Paragraph 51 of Plaintiffs' Complaint properly characterize the contents of the research proposal and refer to the text of the research proposal for its full and correct contents. To the extent not

specifically admitted, Defendants deny all remaining allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Defendants admit that Dr. Simmons provided a written research proposal to Defendants bearing a date of April 5, 1991, but Defendants deny that the allegations in Paragraph 52 of Plaintiffs' Complaint properly characterize the contents of the research proposal and refer to the text of the research proposal for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Defendants admit that Dr. Needleman sent a letter to Dr. Simmons dated April 9, 2001, indicating that he "enjoyed [Dr. Simmons's] seminar and [was] interested in discussing collaboration and support" in the form of a two-year research grant for \$40,000 per year plus indirect costs. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 53 of Plaintiffs' Complaint.

54. Defendants admit that, after Dr. Simmons's seminar and meetings at Searle/1933 Monsanto's corporate headquarters, Searle/1933 Monsanto sent a proposed research agreement to BYU as reflected by a cover letter dated April 11, 1991, from L.R. Swaney to Dr. Simmons, indicating that Dr. Simmons would need to prepare the "description of the project which is to be attached as Appendix 'A' of the agreement." To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 54 of Plaintiffs' Complaint.

55. Although Defendants admit that the Research Agreement followed the "spirit" of the agreement between Searle/1933 Monsanto and Washington University, Defendants deny that Dr. Needleman represented that to BYU that he was offering the "same agreement" that Searle

gave him. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 55 of Plaintiffs' Complaint.

56. Defendants admit that Drs. Seibert and Masferrer met with Dr. Simmons during a 1991 conference in Atlanta. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 56 of Plaintiffs' Complaint.

57. Defendants deny each and every allegation contained in Paragraph 57 of Plaintiffs' Complaint.

58. Defendants deny each and every allegation contained in Paragraph 58 of Plaintiffs' Complaint.

59. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 59 of Plaintiffs' Complaint, and therefore deny them.

60. Defendants deny each and every allegation contained in Paragraph 60 of Plaintiffs' Complaint.

61. Defendants deny that the allegations in Paragraph 61 properly quote or characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. Defendants deny all remaining allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants deny each and every allegation contained in Paragraph 62 of Plaintiffs' Complaint.

63. Defendants deny each and every allegation contained in Paragraph 63 of Plaintiffs' Complaint.

64. Defendants deny each and every allegation contained in Paragraph 64 of Plaintiffs' Complaint.

65. To the extent "Monsanto" in Paragraph 65 refers to 1933 Monsanto, Defendants admit that Dr. Needleman signed the Research Agreement for Searle/1933 Monsanto and that J. Bevan Ott signed the Research Agreement. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 65 of Plaintiffs' Complaint.

66. Defendants admit that the phrase quoted in Paragraph 66 of Plaintiffs' Complaint appears in ¶ 1.1 of the Research Agreement, but Defendants deny that the allegations in Paragraph 66 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Defendants admit that the sentences quoted in Paragraph 67 of Plaintiffs' Complaint appear in Appendix A of the Research Agreement, but Defendants deny that the allegations in Paragraph 67 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 67 of Plaintiffs' Complaint.

68. Defendants admit that Appendix A mentions cancer, wound healing, bone resorption, and ovulation, but Defendants deny that the allegations in Paragraph 68 of Plaintiffs' Complaint properly characterize the contents of the Appendix A of the Research Agreement, and Defendants refer to the text of Research Agreement for its full and correct contents. To the

extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 68 of Plaintiffs' Complaint.

69. Defendants admit that the phrase quoted in Paragraph 69 of Plaintiffs' Complaint appears in ¶ 1.3 of the Research Agreement, but Defendants deny that the allegations in Paragraph 69 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Defendants admit that the phrase quoted in Paragraph 70 of Plaintiffs' Complaint appears in ¶ 1.5 of the Research Agreement, but Defendants deny that the allegations in Paragraph 70 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. Defendants deny that the allegations in Paragraph 71 properly quote or characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. Defendants deny all remaining allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. Defendants deny each and every allegation contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants admit that the phrases quoted in Paragraph 73 of Plaintiffs' Complaint appear in ¶¶ 1.2 and 4.1 of the Research Agreement, but Defendants deny that the allegations in

Paragraph 73 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants admit that Dr. Simmons and Dr. Seibert spoke via telephone. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants admit that the text quoted in Paragraph 75 of Plaintiffs' Complaint appears in ¶ 4.1 of the Research Agreement, but Defendants deny that the allegations in Paragraph 75 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants deny each and every allegation contained in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants admit that the text quoted in Paragraph 77 of Plaintiffs' Complaint appears in ¶¶ 1.3, 3.3, 3.4, 3.5, and 3.6 of the Research Agreement, but Defendants deny that the allegations in Paragraph 77 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants deny each and every allegation contained in Paragraph 78 of Plaintiffs' Complaint.

79. Defendants deny each and every allegation contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 80 of Plaintiffs' Complaint, and therefore deny them.

81. Defendants deny each and every allegation contained in Paragraph 81 of Plaintiffs' Complaint.

82. Defendants deny each and every allegation contained in Paragraph 82 of Plaintiffs' Complaint.

83. Defendants deny each and every allegation contained in Paragraph 83 of Plaintiffs' Complaint.

84. Defendants deny each and every allegation contained in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants deny each and every allegation contained in Paragraph 85 of Plaintiffs' Complaint.

86. Defendants admit between January 8 and 11, 1992, Dr. Simmons and Dr. Seibert each attended at least some portion of a conference in Keystone, Colorado. Defendants further admit that Dr. William Galbraith made a seminar presentation at the conference in Keystone on the patented compound, DuP-697, and that papers related to the seminar indicate Dr. Galbraith

was working for DuPont-Merck. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 86 of Plaintiffs' Complaint.

87. Defendants admit that Dr. Galbraith explained that DuP-697 acted to reduce pain and inflammation but did not cause ulcers in test animals. Defendants further admit that DuP-697 had not been marketed or approved as a non-steroidal anti-inflammatory drug. Upon information and belief, Defendants admit that DuP-697 possessed properties that made it unsuitable for use as a non-steroidal anti-inflammatory drug. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 87 of Plaintiffs' Complaint.

88. Defendants object to the use of the term "NSAID" in Paragraph 88 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that Dr. Seibert recognized that DuP-697 might be a cyclooxygenase-2 selective compound. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 88 regarding Dr. Simmons's beliefs regarding DuP-697. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 89 of Plaintiffs' Complaint, and therefore deny them.

90. Defendants admit that DuP-697 was tested using assays, at least some of which were developed at Washington University and later used at Searle/1933 Monsanto. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Defendants admit that structure activity relationship studies are a common technique for developing compounds. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 91 regarding Dr. Simmons's knowledge, and therefore deny them. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Defendants deny each and every allegation contained in Paragraph 92 of Plaintiffs' Complaint.

93. Defendants deny each and every allegation contained in Paragraph 93 of Plaintiffs' Complaint.

94. Defendants admit that the phrase quoted in Paragraph 94 of Plaintiffs' Complaint appears in ¶ 4.1 of the Research Agreement, but Defendants deny that the allegations in Paragraph 94 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 94 of Plaintiffs' Complaint.

95. Defendants deny each and every allegation contained in Paragraph 95 of Plaintiffs' Complaint.

96. Defendants object to the allegations contained in Paragraph 96 of Plaintiffs' Complaint to the extent they require Defendants to assume that the United States Patent and Trademark Office ("PTO") would have issued any such patents to Dr. Simmons. Defendants further state that the allegations of Paragraph 96 of Plaintiffs' Complaint call for legal

conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation in Paragraph 96 of Plaintiffs' Complaint.

97. Defendants deny that they fraudulently misrepresented anything to Dr. Simmons. Defendants state that the remaining allegations of Paragraph 97 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny these remaining allegations in Paragraph 97 of Plaintiffs' Complaint.

98. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 98 regarding who first isolated or purified cyclooxygenase-2 or isolated and purified the cyclooxygenase-2 gene sequence, and therefore deny them. Defendants state that the remaining allegations of Paragraph 98 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny these remaining allegations in Paragraph 98 of Plaintiffs' Complaint.

99. Defendants deny each and every allegation contained in Paragraph 99 of Plaintiffs' Complaint.

100. Defendants admit that individuals from the University of Rochester were named on a patent (United States Patent Number 6,048,850) that related to cyclooxygenase-2 technology and that the patent was later found to be invalid. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 917 (Fed. Cir. 2004). Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 100 of Plaintiffs' Complaint concerning BYU and Dr. Simmons's knowledge, and therefore deny them.

To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Defendants deny that the allegations in Paragraph 101 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. Defendants deny all remaining allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 102 of Plaintiffs' Complaint concerning Plaintiffs' knowledge or experience, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Defendants deny each and every allegation contained in Paragraph 103 of Plaintiffs' Complaint.

104. Defendants admit that from August 1, 1991 to March 27, 1992, the Research Agreement was in effect and that Dr. Bradshaw visited Searle/1933 Monsanto. Defendants deny all remaining allegations contained in Paragraph 104 of Plaintiffs' Complaint.

105. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 105 of Plaintiffs' Complaint concerning Dr. Simmons's telephone records. Defendants deny all remaining allegations contained in Paragraph 105 of Plaintiffs' Complaint.

106. Defendants admit that Dr. Needleman sent a letter to Dr. Simmons dated March 17, 1992, advising him that "we should give serious consideration to ending the grant at the end of one year," but Defendants deny that the allegations in Paragraph 106 properly characterize the

contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. Defendants admit that Dr. Simmons sent Dr. Needleman a letter dated March 20, 1992, but Defendants deny that the allegations in Paragraph 107 properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 107 of Plaintiffs' Complaint.

108. Defendants admit that the phrase quoted in Paragraph 108 of Plaintiffs' Complaint appears in a letter dated March 23, 1992, from Dr. Needleman to Dr. Simmons, but Defendants deny that the allegations in Paragraph 108 properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 108 of Plaintiffs' Complaint.

109. Defendants admit that BYU sent a letter to Searle/1933 Monsanto dated March 27, 1992, agreeing to the termination of the Research Agreement, but Defendants deny that the allegations in Paragraph 109 properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 109 of Plaintiffs' Complaint.

110. Defendants deny each and every allegation contained in Paragraph 110 of Plaintiffs' Complaint.

111. Defendants admit that the phrase quoted in Paragraph 111 of Plaintiffs' Complaint appears in a letter dated May 20, 1992, from Dr. Simmons to Dr. Needleman, but Defendants deny that the allegations in Paragraph 111 properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 111 of Plaintiffs' Complaint.

112. Defendants admit that Dr. Simmons accompanied his May 20, 1992 letter with a "post-termination report." Defendants deny all remaining allegations contained in Paragraph 112 of Plaintiffs' Complaint.

113. Defendants deny each and every allegation contained in Paragraph 113 of Plaintiffs' Complaint.

114. Defendants deny each and every allegation contained in Paragraph 114 of Plaintiffs' Complaint.

115. Defendants deny each and every allegation contained in Paragraph 115 of Plaintiffs' Complaint.

116. Defendants deny each and every allegation contained in Paragraph 116 of Plaintiffs' Complaint.

117. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 117 of Plaintiffs' Complaint regarding Dr. Simmons attendance at the "International Conference on Prostaglandins and Related Compounds" from July 26-31, 1992, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 117 of Plaintiffs' Complaint.

118. Defendants deny each and every allegation contained in Paragraph 118 of Plaintiffs' Complaint.

119. Defendants deny each and every allegation contained in Paragraph 119 of Plaintiffs' Complaint.

120. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 120 regarding Dr. Simmons's knowledge of Searle/1933 Monsanto's testing and development of compounds, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Defendants admit that Searle/1933 Monsanto's reasons for terminating the Research Agreement were not false and that Searle/1933 Monsanto had done nothing wrong in connection with its relationships to Dr. Simmons and BYU. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants deny each and every allegation contained in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants deny each and every allegation contained in Paragraph 123 of Plaintiffs' Complaint.

124. Defendants deny each and every allegation contained in Paragraph 124 of Plaintiffs' Complaint.

125. Defendants deny each and every allegation contained in Paragraph 125 of Plaintiffs' Complaint.

126. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 126 of Plaintiffs' Complaint regarding whether Dr. Simmons attended a prostaglandin conference in Cannes, France, in March of 1997, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny each and every allegation contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants admit that Dr. Needleman was the first to discover cyclooxygenase-2 and that members of the scientific community have recognized Dr. Needleman's discovery. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants admit that, prior to the attempts to resolve this dispute Dr. Simmons did not have access to the internal scientific documentation at Searle/1933 Monsanto. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants admit that U.S. Patent Number 5,420,343 dated May 30, 1995, and United States Patent Number 5,476,944 dated December 19, 1995, indicate that the cell testing systems were constructed using human or murine cyclooxygenase-1 or cyclooxygenase-2 fragments from "Cayman Chemical, Ann Arbor, Mich." To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny each and every allegation contained in Paragraph 131 of Plaintiffs' Complaint.

132. Defendants object to the use of the term "NSAID" in Paragraph 132 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that on June 29, 1998, Searle/1933 Monsanto submitted its New Drug Application for Celebrex for "priority review." To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Defendants admit that on December 1, 1998, Searle/1933 Monsanto presented slides showing Celebrex would inhibit cyclooxygenase-2, but not cyclooxygenase-1, in certain assays, to an independent Arthritis Advisory Committee, which made recommendations to the FDA that the FDA could accept or deny. Defendants further admit that the phrases quoted in Paragraph 133 of Plaintiffs' Complaint appear in statements made by Dr. Needleman to the FDA, but Defendants deny that the allegations in Paragraph 133 properly characterize the contents of the statements and refer to the text of the statements for their full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 133 of Plaintiffs' Complaint.

134. Defendants admit that Dr. Needleman and his colleagues independently discovered and identified cyclooxygenase-2 and announced the possibility of a selective inhibitor long before meeting Dr. Simmons. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants deny each and every allegation contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants deny each and every allegation contained in Paragraph 136 of Plaintiffs' Complaint.

137. Defendants admit that the excerpted phrases quoted in Paragraph 137 of the Complaint were taken from a July 8, 1996 MS Press Wire Release and that the press release does not mention that Dr. Simmons first identified cyclooxygenase-2 or that Monsanto misappropriated the PROJECT (because any such statement would be false). Defendants deny that the allegations in Paragraph 137 of Plaintiffs' Complaint properly characterize the contents of the July 8, 1996 MS Press Wire Release, and therefore deny those allegations. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants admit that the excerpted phrases quoted in Paragraph 138 of the Complaint were taken from a 1996 annual report to shareholders, filed with the Securities and Exchange Commission on March 21, 1997. Defendants deny that the allegations in Paragraph 138 of Plaintiffs' Complaint properly characterize the contents of the 1996 annual report to shareholders, and therefore deny those allegations. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Defendants object to the use of the term "NSAID" in Paragraph 139 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit Dr. Needleman and other Searle/1933 Monsanto scientists discovered cyclooxygenase-2, conceived the idea of a cyclooxygenase-2 selective inhibitor project, and pioneered the testing system that led to a cyclooxygenase-2 selective medicine. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. Defendants admit that the excerpted phrases quoted in Paragraph 140 of Plaintiffs' Complaint were taken from the cited articles, press releases, and statement before the Labor,

Health and Human Services, and Education Subcommittee. Defendants deny that the allegations in Paragraph 140 of Plaintiffs' Complaint properly characterize the contents of the cited articles, press releases, and subcommittee statement, and therefore deny those allegations. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants object to the use of the term "NSAID" in Paragraph 141 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that Dr. Needleman represented publicly that he and his colleagues had independently discovered cyclooxygenase-2 and had conceived the concept of a cyclooxygenase-2 selective inhibitor. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 142 of Plaintiffs' Complaint, and therefore deny them.

143. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Dr. Simmons dealings with BYU's General Counsel's office, and therefore deny them. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants deny each and every allegation contained in Paragraph 144 of Plaintiffs' Complaint.

145. Defendants deny each and every allegation contained in Paragraph 145 of Plaintiffs' Complaint.

146. To the extent "Monsanto" in Paragraph 146 refers to 1933 Monsanto, Defendants admit the allegations contained in Paragraph 146 of Plaintiffs' Complaint. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 147 of Plaintiffs' Complaint, and therefore deny them.

148. To the extent "Monsanto" in Paragraph 148 refers to 1933 Monsanto, Defendants admit the allegations contained in Paragraph 148 of Plaintiffs' Complaint. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 148 of Plaintiffs' Complaint.

149. To the extent "Monsanto" in Paragraph 149 refers to 1933 Monsanto, Defendants admit the allegations contained in Paragraph 149 of Plaintiffs' Complaint. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 149 of Plaintiffs' Complaint.

150. Defendants admit that BYU's counsel and Dr. Simmons sent Searle/1933 Monsanto a letter dated March 29, 2000, and that the letter contained fifteen numbered "Questions and Requests." Defendants also admit that Dale H. Hoscheit, counsel for Searle/1933 Monsanto, sent a letter dated May 17, 2000, to David Thomas of the Office of General Counsel at BYU. Defendants further admit that the parties agreed to meet in Skokie, Illinois, in June of 2000. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants admit that at the meeting in Skokie, Illinois, Searle/1933 Monsanto gave BYU limited access to Dr. Seibert's notebooks, which demonstrated that Searle/1933 Monsanto had not used Dr. Simmons's research and tools in developing Celebrex. Defendants further admit that they used binder clips to seal portions of Dr. Seibert's notebooks that related to other confidential projects. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 151 of Plaintiffs' Complaint. Furthermore, to the extent the Paragraph 151 of the Complaint refers to confidential documents and information obtained by Plaintiffs in other litigation subject to a protective order (or pursuant to a confidentiality agreement in the present dispute), the allegations contained in Paragraph 151 of Plaintiffs' Complaint are denied as improper.

152. Defendants deny each and every allegation contained in Paragraph 152 of Plaintiffs' Complaint.

153. Defendants admit that Dr. Simmons and Dr. Seibert had a discussion in which Dr. Seibert explained that Dr. Simmons's clones had not worked in her experiments. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. Defendants admit that Monsanto Company and G.D. Searle & Co. entered into a tolling agreement with BYU and Dr. Simmons bearing a date of May 8, 2001; however, Defendants deny the validity of the tolling agreement in light of its indefinite duration and deny that the tolling agreement preserved any of Plaintiffs' claims against Defendants. Defendants further admit that Plaintiffs and Defendants have attempted to mediate this dispute; however, Defendants deny that Plaintiffs' attempt at mediation was reasonable and further deny the

reasonableness of Plaintiffs' delay in filing their Complaint until nearly nine months following their last recent mediation attempt. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 154 of Plaintiffs Complaint regarding whether BYU became alerted to the alleged need to begin investigative efforts in June 2000, and therefore deny them. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 154 of Plaintiffs' Complaint.

155. Defendants object to the use of the term "launched" in Paragraph 155 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that the New Drug Application for Celebrex was approved by the FDA on December 31, 1998, and Celebrex was launched shortly thereafter. Defendants further admit that they have been involved in various lawsuits to enforce the Celebrex patent and that one or more of the Defendants have initiated some, but not all, of the lawsuits involving Merck's patents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 155 of Plaintiffs' Complaint.

156. Defendants object to the use of the terms "NSAID" and "launched" in Paragraph 156 of Plaintiffs' Complaint as vague and ambiguous. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 156 of Plaintiffs' Complaint regarding Merck activities with respect to Vioxx, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 156 of Plaintiffs' Complaint.

157. Defendants admit that G.D. Searle & Co., Monsanto Company, Pharmacia Corporation, and Pfizer Inc. were sued by the University of Rochester on April 11, 2000, and

that the University of Rochester claimed that Celebrex violated a University of Rochester cyclooxygenase-2 related patent. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). On information and belief, Defendants admit that the PTO declared an interference action between the University of Rochester and Merck, Interference Number 104,289, which was decided on November 21, 2000. *See Cromlish v. Young*, 57 U.S.P.Q. 2d 1318 (Bd. Pat. App. & Int. 2000). Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 157 of Plaintiffs' Complaint, and therefore deny them.

158. Defendants admit that a subpoena was served on Dr. Simmons in the Rochester v. Searle litigation and that Dr. Simmons was deposed as a fact witness in that litigation. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 158 of Plaintiffs' Complaint regarding whether various parties to lawsuits approached Dr. Simmons and asked him to testify, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 158 of Plaintiffs' Complaint.

159. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 159 regarding whether Dr. Simmons participated in the lawsuits referenced in Paragraph 158 of Plaintiffs' Complaint and received Searle/1933 Monsanto documents, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 159 of Plaintiffs' Complaint. Furthermore, to the extent Paragraph 159 refers to confidential documents and information obtained by Plaintiffs in other litigations subject to a protective order, the allegations contained in Paragraph 159 of Plaintiffs' Complaint are denied as improper.

160. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 160 of Plaintiffs' Complaint concerning the actions of Dr. Simmons and BYU's General Counsel, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 160 of Plaintiffs' Complaint.

161. Defendants admit that the phrase quoted in Paragraph 161 of Plaintiffs' Complaint appears in a witness statement of Dr. Peter Isakson, but Defendants deny that the allegations in Paragraph 161 properly characterize the contents of the witness statement, and therefore deny this allegation. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 161 of Plaintiffs' Complaint regarding what Dr. Simmons was shown or read, and therefore deny them. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 161 of Plaintiffs' Complaint.

162. Defendants admit that the phrase quoted in Paragraph 162 of Plaintiffs' Complaint appears in the testimony by Dr. Isakson, but Defendants deny that the allegations in the Complaint properly characterize the contents of the testimony, and therefore deny this allegation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 162 of Plaintiffs' Complaint.

163. Defendants admit that the phrases quoted in Paragraph 163 of Plaintiffs' Complaint appear in the testimony by Dr. Peter Isakson, but Defendants deny that the allegations in Paragraph 163 properly characterize the contents of the testimony, and therefore deny this allegation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 163 of Plaintiffs' Complaint.

164. Defendants object to the use of the term "NSAID" in Paragraph 164 of Plaintiffs' Complaint as vague and ambiguous. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 164 of Plaintiffs' Complaint regarding how Dr. Simmons perceived Dr. Isakson's testimony, and therefore deny them. Defendants deny all remaining allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. Defendants admit that the phrase quoted in Paragraph 165 of Plaintiffs' Complaint appears in the testimony by Dr. Isakson, but Defendants deny that the allegations in Paragraph 165 properly characterize the contents of the testimony, and therefore deny this allegation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 165 of Plaintiffs' Complaint.

166. Defendants object to the use of the term "NSAIDs" and the phrase "the two cell assay" in Paragraph 166 of Plaintiffs' Complaint as vague and ambiguous. Defendants deny each and every allegation contained in Paragraph 166 of Plaintiffs' Complaint.

167. Defendants admit that the phrase quoted in Paragraph 167 of Plaintiffs' Complaint appears in a document entitled "Memorandum of Law in Support of Plaintiff University of Rochester's Motion to Compel Defendant G.D. Searle & Co., Inc. to Produce Documents," which was filed in 2001 by Defendants' adversary, University of Rochester, in unrelated litigation. Defendants deny, however, that the quoted phrase properly characterizes Defendants' position in that litigation. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 167 of Plaintiffs' Complaint.

168. Defendants deny each and every allegation contained in Paragraph 168 of Plaintiffs' Complaint.

169. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 169 of Plaintiffs' Complaint, and therefore deny them.

COUNT I
(BREACH OF WRITTEN CONTRACT)

170. Defendants repeat and reallege each and every answer to Paragraphs 1 through 169 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

171. Defendants admit that ¶ 1.3 of the Research Agreement states, in part, that the "PROJECT and all work assigned shall be carried out under the direction of Dr. Daniel L. Simmons." Defendants deny, however, that the allegations in Paragraph 171 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 171 of Plaintiffs' Complaint.

172. Defendants deny each and every allegation contained in Paragraph 172 of Plaintiffs' Complaint.

173. Defendants object to the use of the term "NSAIDs" in Paragraph 173 of Plaintiffs' Complaint as vague and ambiguous. Defendants admit that Paragraph 173 of Plaintiffs' Complaint references ¶ 1.6 of the Research Agreement, which states, in part, that "MONSANTO shall furnish prostaglandins, NSAIDs and consulting services to the extent provided in Appendix 'A'" Defendants deny, however, that the allegations in Paragraph 173 properly characterize

the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. Defendants deny each and every allegation contained in Paragraph 174 of Plaintiffs' Complaint.

175. Defendants admit that Paragraph 175 of Plaintiffs' Complaint references ¶ 3.1 of the Research Agreement, which states, in part, that "[t]itle to all discoveries and inventions, whether or not patentable or patented shall be as follows." Defendants deny, however, that the allegations in Paragraph 175 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 175 of Plaintiffs' Complaint.

176. Defendants admit that ¶ 3.1 of the Research Agreement states, in part, that "[i]f one or more UNIVERSITY personnel only are inventors, title shall belong to UNIVERSITY" Defendants deny, however, that the allegations in Paragraph 176 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 176 of Plaintiffs' Complaint.

177. Defendants admit that ¶ 3.1 of the Research Agreement states, in part, that "if one or more MONSANTO personnel only are inventors, title shall belong to MONSANTO." Defendants deny, however, that the allegations in Paragraph 177 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full

and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 177 of Plaintiffs' Complaint.

178. Defendants admit that ¶ 3.1 of the Research Agreement states, in part, that "if one or more personnel of UNIVERSITY and MONSANTO are joint inventors, title shall belong jointly to UNIVERSITY and MONSANTO." Defendants deny, however, that the allegations in Paragraph 178 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 178 of Plaintiffs' Complaint.

179. Defendants deny each and every allegation contained in Paragraph 179 of Plaintiffs' Complaint.

180. Defendants admit that ¶ 3.3 of the Research Agreement states, in part, that "[i]n the event that MONSANTO determines that research results obtained from the PROJECT are patentable, it shall notify UNIVERSITY and thereafter indicate to UNIVERSITY its interest in a license under such prospective patents." Defendants deny, however, that the allegations in Paragraph 180 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 180 of Plaintiffs' Complaint.

181. Defendants deny each and every allegation contained in Paragraph 181 of Plaintiffs' Complaint.

182. Defendants admit that ¶ 3.4 of the Research Agreement states, in part, that "UNIVERSITY agrees to negotiate in good faith with MONSANTO the terms and conditions of a royalty-bearing license agreement with a right to sublicense with respect to patented inventions developed in the PROJECT." Defendants deny, however, that the allegations in Paragraph 182 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 182 of Plaintiffs' Complaint.

183. Defendants deny each and every allegation contained in Paragraph 183 of Plaintiffs' Complaint.

184. Defendants admit that ¶ 3.5 of the Research Agreement states, in part, that "[w]ith regard to prospective patent rights referred to in paragraph 3.3, UNIVERSITY shall have the right to designate, at its sole option, either MONSANTO's Patent Department or a patent attorney in private practice to prepare, file and prosecute patent applications." Defendants deny, however, that the allegations in Paragraph 184 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 184 of Plaintiffs' Complaint.

185. Defendants deny each and every allegation contained in Paragraph 185 of Plaintiffs' Complaint.

186. Defendants admit that ¶ 3.6 of the Research Agreement states, in part, that "MONSANTO agrees to bear the cost for filing and prosecution of patent applications under paragraph 3.5 and the issuance and maintenance of patents thereon." Defendants deny, however,

that the allegations in Paragraph 186 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 186 of Plaintiffs' Complaint.

187. Defendants deny each and every allegation contained in Paragraph 187 of Plaintiffs' Complaint.

188. Defendants admit that the phrases quoted in Paragraph 188 of Plaintiffs' Complaint appear in ¶ 3.7 of the Research Agreement, but Defendants deny that the allegations in Paragraph 188 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 188 of Plaintiffs' Complaint.

189. Defendants deny each and every allegation contained in Paragraph 189 of Plaintiffs' Complaint.

190. Defendants admit that ¶ 3.11 of the Research Agreement states, in part, that "[l]icense granted to MONSANTO under this Article 3 shall contain at least the requirements that MONSANTO, by its own efforts or through sublicenses during the period of exclusivity, make reasonable efforts to effect the lawful introduction of licensed products into the market place as early as practicable consistent with MONSANTO'S sound and reasonable business practice and judgment." Defendants deny, however, that the allegations in Paragraph 190 properly characterize the contents of the Research Agreement and refer to the text of the

Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 190 of Plaintiffs' Complaint.

191. Defendants deny each and every allegation contained in Paragraph 191 of Plaintiffs' Complaint.

192. Defendants admit that the Paragraph ¶ 4.1 of the Research Agreement states, in part, that the parties will:

"(1) hold any and all CONFIDENTIAL INFORMATION received pursuant to this Agreement in confidence, and not to disclose such information to third parties without the written consent of the other,

(2) limit the disclosure of CONFIDENTIAL INFORMATION to those personnel who need such access for purpose of this cooperative effort and who have undertaken the obligation to restrict the use and disclosure of CONFIDENTIAL INFORMATION to the extent provided by this Article 4, and

(3) not duplicate or use CONFIDENTIAL INFORMATION in any other manner"

Defendants, however, deny that the allegations in Paragraph 192 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 192 of Plaintiffs' Complaint.

193. Defendants deny each and every allegation contained in Paragraph 193 of Plaintiffs' Complaint.

194. Defendants deny each and every allegation contained in Paragraph 194 of Plaintiffs' Complaint.

195. Defendants admit that ¶ 4.2 of the Research Agreement states, in part, that "[n]either party shall furnish to any third party, without the other party's prior written consent, any chemical or biological material including DNA sequences and vectors supplied by the other party under this Agreement unless such material falls within the scope of the licenses granted herein in Article 3." Defendants deny, however, that the allegations in Paragraph 195 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 195 of Plaintiffs' Complaint.

196. Defendants deny each and every allegation contained in Paragraph 196 of Plaintiffs' Complaint.

197. Defendants admit that ¶ 1.4 of the Research Agreement states that "[t]he PROJECT covered by this Agreement extends for a period of two (2) years commencing on August 1, 1991 and continuing though July 31, 1993." Defendants deny, however, that the allegations in Paragraph 197 properly characterize the contents of the Research Agreement and refer to the text of the Research Agreement for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 197 of Plaintiffs' Complaint.

198. Defendants deny each and every allegation contained in Paragraph 198 of Plaintiffs' Complaint.

199. Defendants deny each and every allegation contained in Paragraph 199 of Plaintiffs' Complaint.

200. Defendants deny each and every allegation contained in Paragraph 200 of Plaintiffs' Complaint.

COUNT II
(BREACH OF DUTY OF GOOD FAITH AND FAIR DEALING)

201. Defendants repeat and reallege each and every answer to Paragraphs 1 through 200 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

202. Defendants state that the allegations of Paragraph 202 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 202 of Plaintiffs' Complaint.

203. Defendants deny each and every allegation contained in Paragraph 203 of Plaintiffs' Complaint.

204. Defendants deny each and every allegation contained in Paragraph 204 of Plaintiffs' Complaint.

COUNT III
(BREACH OF FIDUCIARY DUTY)

205. Defendants repeat and reallege each and every answer to Paragraphs 1 through 204 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

206. Defendants state that the allegations of Paragraph 206 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 206 of Plaintiffs' Complaint.

207. Defendants state that the allegations of Paragraph 207 of Plaintiffs' Complaint call for legal conclusions to which no response is required. To the extent a response is required, Defendants deny each and every allegation contained in Paragraph 207 of Plaintiffs' Complaint.

208. Defendants deny each and every allegation contained in Paragraph 208 of Plaintiffs' Complaint.

209. Defendants deny each and every allegation contained in Paragraph 209 of Plaintiffs' Complaint.

210. Defendants deny each and every allegation contained in Paragraph 210 of Plaintiffs' Complaint.

211. Defendants deny each and every allegation contained in Paragraph 211 of Plaintiffs' Complaint.

212. Defendants deny each and every allegation contained in Paragraph 212 of Plaintiffs' Complaint.

COUNT IV
(CORRECTION OF INVENTORSHIP UNDER 35 U.S.C. § 256)

(United States Patent Nos. 5,380,738; 5,393,790; 5,418,254; 5,420,343; 5,466,823; 5,476,944; 5,486,534; 5,547,975; 5,563,165; 5,565,482; 5,576,339; 5,580,985; 5,596,008; 5,616,601; 5,620,999; 5,633,272; 5,643,933; 5,663,180; 5,668,161; 5,670,510; 5,670,532; 5,672,626; 5,672,627; 5,686,470; 5,696,143; 5,719,163; 5,736,579; 5,739,166; 5,756,529; 5,756,530; 5,760,068; 5,859,257; 5,886,016; 5,908,852; 5,916,905; 5,935,990; 5,985,902; 6,028,072; 6,034,256; 6,077,850; 6,090,834; 6,156,781; 6,271,253; 6,274,590; 6,395,724; 6,413,960; 6,426,360; 6,432,999; 6,492,390; 6,492,411; 6,492,413; 6,512,121; 6,515,014; 6,586,603; 6,599,934; 6,613,789; 6,613,790; 6,649,636; 6,649,649; 6,673,818; 6,677,364; 6,677,488; 6,696,477; 6,699,884; 6,716,991; 6,753,344; 6,806,288; 6,809,111; 6,822,102; 6,846,818; 6,875,785; 6,951,949; 6,964,978; 7,012,094; 7,030,153)

213. Defendants repeat and reallege each and every answer to Paragraphs 1 through 212 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

214. Defendants admit that Bryan H. Norman, Len F. Lee, Jaime L. Masferrer, and John J. Talley, through their patent agents, filed various applications in the PTO for issuance of one or more United States patents and that the PTO eventually granted some of these applications. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 214 of Plaintiffs' Complaint.

215. Defendants deny each and every allegation contained in Paragraph 215 of Plaintiffs' Complaint.

216. Defendants deny each and every allegation contained in Paragraph 216 of Plaintiffs' Complaint.

217. Defendants admit that Dr. Simmons was not named as an inventor on any of the patents listed above. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 217 of Plaintiffs' Complaint.

218. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 218 of Plaintiffs' Complaint regarding the intent of BYU and Dr. Simmons, and therefore deny them. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Paragraph 218 of Plaintiffs' Complaint.

219. Defendants deny each and every allegation contained in Paragraph 219 of Plaintiffs' Complaint.

COUNT V
(UNJUST ENRICHMENT)

220. Defendants repeat and reallege each and every answer to Paragraphs 1 through 219 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

221. Defendants deny each and every allegation contained in Paragraph 221 of Plaintiffs' Complaint.

222. Defendants deny each and every allegation contained in Paragraph 222 of Plaintiffs' Complaint.

223. Defendants deny each and every allegation contained in Paragraph 223 of Plaintiffs' Complaint.

224. Defendants deny each and every allegation contained in Paragraph 224 of Plaintiffs' Complaint.

COUNT VI
(FRAUD)

225. Defendants repeat and reallege each and every answer to Paragraphs 1 through 224 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

226. Defendants deny each and every allegation contained in Paragraph 226, in its entirety, as set forth in Plaintiffs' Complaint. Specifically, Defendants deny the factual assertions in each of the following Subparagraphs of Paragraph 226 of Plaintiffs' Complaint:

- (a) Defendants deny each and every allegation contained in Subparagraph 226(a) of Plaintiffs' Complaint.

- (b) Although Defendants admit that the Research Agreement followed the "spirit" of the agreement between Monsanto and Washington University, Defendants deny that Dr. Needleman represented that to BYU that he was offering the "same agreement" that Monsanto gave him when he was a professor at Washington University. Defendants deny each and every remaining allegation contained in Subparagraph 226(b) of Plaintiffs' Complaint.
- (c) Defendants admit that Subparagraph 226(c) of Plaintiff's Complaint references a letter dated March 17, 1992, from Dr. Needleman to Dr. Simmons, but Defendants deny that the allegations in Subparagraph 226(c) properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 226(c) of Plaintiffs' Complaint.
- (d) Defendants admit that Subparagraph 226(d) of Plaintiffs' Complaint references a letter dated March 23, 1992, from Dr. Needleman to Dr. Simmons, but Defendants deny that the allegations in Subparagraph 226(d) properly characterize the contents of the letter and refer to the text of the letter for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 226(d) of Plaintiffs' Complaint.
- (e) Defendants deny each and every allegation contained in Subparagraph 226(e) of Plaintiffs' Complaint.
- (f) Defendants admit that Searle/1933 Monsanto acted honestly with respect to the PROJECT and that termination of the Research Agreement. To the extent not

specifically admitted, Defendants deny all remaining allegations contained in Paragraph 226(f) of Plaintiffs' Complaint.

- (g) Defendants deny each and every allegation contained in Subparagraph 226(g) and the allegations "as described earlier in this Complaint."
- (h) Defendants admit that Searle/1933 Monsanto patents, 5,420,343 dated May 30, 1995, and 5,476,944 dated December 19, 1995, indicate that the cell testing systems were constructed using human or murine COX-1 or COX-2 fragments from "Cayman Chemical, Ann Arbor, Mich." To the extent not specifically admitted, Defendants deny each and every allegation contained in Subparagraph 226(h) and the allegations "as described earlier in this Complaint."
- (i) Defendants deny each and every allegation contained in Subparagraph 226(i) and the allegations "as described above in Section V(E)" of Plaintiffs' Complaint.
- (j) Defendants admit that the phrase quoted in Paragraph 226(j) of Plaintiffs' Complaint appears in a 1996 annual report to shareholders, filed with the Securities and Exchange Commission on March 21, 1997, but Defendants deny that the allegations in Paragraph 226(j) properly characterize the contents of the 1996 annual report and refer to the text of the 1996 annual report for its full and correct contents. To the extent not specifically admitted, Defendants deny all remaining allegations contained in Subparagraph 226(j) of Plaintiffs' Complaint.
- (k) Defendants deny each and every allegation contained in Subparagraph 226(k) of Plaintiffs' Complaint.

227. Defendants deny each and every allegation contained in Paragraph 227 of Plaintiffs' Complaint.

228. Defendants deny each and every allegation contained in Paragraph 228 of Plaintiffs' Complaint.

229. Defendants deny each and every allegation contained in Paragraph 229 of Plaintiffs' Complaint.

230. Defendants deny each and every allegation contained in Paragraph 230 of Plaintiffs' Complaint.

231. Defendants deny each and every allegation contained in Paragraph 231 of Plaintiffs' Complaint.

232. Defendants deny each and every allegation contained in Paragraph 232 of Plaintiffs' Complaint.

233. Defendants deny each and every allegation contained in Paragraph 233 of Plaintiffs' Complaint.

234. Defendants deny each and every allegation contained in Paragraph 234 of Plaintiffs' Complaint.

235. Defendants deny each and every allegation contained in Paragraph 235 of Plaintiffs' Complaint.

COUNT VII
(NEGLIGENT MISREPRESENTATION)

236. Defendants repeat and reallege each and every answer to Paragraphs 1 through 235 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

237. Defendants deny each and every allegation contained in Paragraph 237 of Plaintiffs' Complaint, alone and as it incorporates COUNT VI (Fraud) above.

238. Defendants deny each and every allegation contained in Paragraph 238 of Plaintiffs' Complaint.

239. Defendants deny each and every allegation contained in Paragraph 239 of Plaintiffs' Complaint.

240. Defendants deny each and every allegation contained in Paragraph 240 of Plaintiffs' Complaint.

241. Defendants deny each and every allegation contained in Paragraph 241 of Plaintiffs' Complaint.

242. Defendants deny each and every allegation contained in Paragraph 242 of Plaintiffs' Complaint.

243. Defendants deny each and every allegation contained in Paragraph 243 of Plaintiffs' Complaint.

COUNT VIII
(VIOLATION OF THE UNIFORM TRADE SECRET ACT,
UTAH CODE ANN. § 13-24-2 *ET SEQ*)

244. Defendants repeat and reallege each and every answer to Paragraphs 1 through 243 of Plaintiffs' Complaint, with the same force and effect as though set forth in their entirety herein.

245. Defendants deny each and every allegation contained in Paragraph 245 of Plaintiffs' Complaint.

246. Defendants deny each and every allegation contained in Paragraph 246 of Plaintiffs' Complaint.

247. Defendants deny each and every allegation contained in Paragraph 247 of Plaintiffs' Complaint.

248. Defendants deny each and every allegation contained in Paragraph 248 of Plaintiffs' Complaint.

249. Defendants deny each and every allegation contained in Paragraph 249 of Plaintiffs' Complaint.

250. Defendants deny each and every allegation contained in Paragraph 250 of Plaintiffs' Complaint.

SPECIAL DEFENSES

By asserting the following special defenses, Defendants do not allege or admit they have the burden of proof and/or the burden of persuasion with respect to any of these matters:

FIRST SPECIAL DEFENSE **(Failure to State a Cause of Action)**

As a first and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' Complaint and each purported claim for relief asserted therein fail to state a claim upon which relief can be granted.

SECOND SPECIAL DEFENSE **(Improper Venue)**

As a second and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because they have been filed in an improper venue. In addition, Plaintiffs' wrongful pretrial publicity campaign has prejudiced the venire, making venue in the State of Utah improper.

THIRD SPECIAL DEFENSE **(Failure to Name Proper Parties)**

As a third and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because the Complaint improperly names two Defendants, Monsanto Company and G.D. Searle & Company. Monsanto Company (referred to herein as "2000 Monsanto") is not a proper party to this matter, because it is engaged in the agricultural business and does not and has not ever developed, manufactured, marketed, sold, or distributed products relevant to this litigation. G.D. Searle &

Company is not a proper party to this matter, because it was converted from a corporation to a limited liability company, G.D. Searle LLC, in January of 2001.

FOURTH SPECIAL DEFENSE
(Invalid and/or Unenforceable Tolling Agreement)

As a fourth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs are barred from bringing suit because the tolling agreement entered into by Plaintiffs and Defendants on May 8, 2001, is invalid and/or unenforceable because it lacks a definite duration and therefore, does not preserve any of Plaintiffs' claims against Defendants.

FIFTH SPECIAL DEFENSE
(Statute of Limitations and/or Repose)

As a fifth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred by the applicable statute of limitations and/or repose. The claims based upon a written contract, obligation, or liability founded upon an instrument in writing are barred by the six-year Utah statute of limitations. The claims based upon a contract, obligation, or liability not founded upon an instrument in writing are barred by the four-year Utah statute of limitations. The claims for relief on the ground of fraud or mistake are barred by the three-year Utah statute of limitations. All other common law claims for relief are barred by the four-year Utah statute of limitations. The Uniform Trade Secret Act claim is barred by the three-year Utah statute of limitations. The claims are also barred by any other applicable statutes of limitations.

SIXTH SPECIAL DEFENSE
(Laches and Waiver)

As a sixth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches and waiver.

SEVENTH SPECIAL DEFENSE
(Equitable Estoppel)

As a seventh and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' alleged claims and any alleged damages are barred, in whole or in part, by the doctrine of equitable estoppel, because Plaintiffs waited until Defendants had expended years of effort and millions of dollars to develop a commercially viable product before claiming any interest in the technology leading to the commercial product Celebrex.

EIGHTH SPECIAL DEFENSE
(Statute of Frauds)

As a eighth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by the statute of frauds.

NINTH SPECIAL DEFENSE
(No Contractual Provision)

As a ninth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because the Research Agreement makes no provision for payments to Plaintiffs for any discovery and invention, whether or not patentable, made by Defendants.

TENTH SPECIAL DEFENSE
(No Contractual Obligation)

As a tenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by the express terms of the Research Agreement.

ELEVENTH SPECIAL DEFENSE
(Specific Contractual Relationship)

As a eleventh and separate defense, and solely by the way of defense and not to be construed as an admission, Defendants allege that the contractual relationship between Searle/1933 Monsanto and Plaintiffs was specifically for the limited purpose set forth therein and did not impose any obligation on Searle/1933 Monsanto to act primarily for Plaintiffs' benefit in any endeavor, or any duty or obligation to seek out, advise, or consult with Plaintiffs regarding Plaintiffs' interests.

TWELFTH SPECIAL DEFENSE
(Breach of Contract)

As a twelfth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' breach of contract.

THIRTEENTH SPECIAL DEFENSE
(Mutual Termination of Contract)

As a thirteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by the agreement of the parties to the mutual termination of the Research Agreement on March 27, 1992, after the Defendants had fully performed their obligations under the Research Agreement.

FOURTEENTH SPECIAL DEFENSE
(Lack of Fiduciary Relationship)

As a fourteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Defendants allege that no fiduciary relationship existed between Plaintiffs and Defendants in any respect, and further, Defendants affirmatively allege that any relationship between Plaintiffs and Defendants was specifically limited to the mutual obligations set forth in the Research Agreement, was fully disclosed and understood by Plaintiffs, and did not involve any agreement or duty on the part of any Defendants to act as fiduciary.

FIFTEENTH SPECIAL DEFENSE
(Failure to Name Real Parties-in-Interest)

As a fifteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claim for correction of inventorship is barred, in whole or in part, and particularly as it relates to United States Patent Numbers 6,395,724 and 6,649,649, by the failure to name the real parties-in-interest.

SIXTEENTH SPECIAL DEFENSE
(Failure to Qualify as an Inventor)

As a sixteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because the sequencing of cyclooxygenase-2 does not qualify Dr. Simmons as an inventor on any patent at issue in this litigation.

SEVENTEENTH SPECIAL DEFENSE
(Lack of Reliance)

As a seventeenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because, in the

development of the commercial product Celebrex, no Defendant relied upon any of the information alleged to have been developed by Dr. Simmons.

EIGHTEENTH SPECIAL DEFENSE
(Release of Information into Public Domain)

As a eighteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, by Dr. Simmons's publication of the nucleic acid sequence of chicken cyclooxygenase-2, which placed that information into the public domain, which anyone was free to use.

NINETEENTH SPECIAL DEFENSE
(Existence of a Valid Contract)

As a nineteenth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claim for unjust enrichment is barred by the existence of a valid contract between Plaintiffs and Defendants and a valid mutual termination of that contract.

TWENTIETH SPECIAL DEFENSE
(Supersedence by Contract)

As a twentieth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because any alleged representations were purported to have occurred prior to the execution of the Research Agreement, and therefore, were superseded by the Research Agreement.

TWENTY-FIRST SPECIAL DEFENSE
(Failure to State Fraud with Particularity)

As a twenty-first and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' fraud-based claims are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

TWENTY-SECOND SPECIAL DEFENSE
(Preemption/Foreclosure)

As a twenty-second and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are preempted or foreclosed by the Uniform Trade Secret Act, Utah Code Ann. § 13-24-2 *et seq.*

TWENTY-THIRD SPECIAL DEFENSE
(Breach of Confidentiality)

As a twenty-third and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have breached confidentiality agreements including, but not limited to, the Letter Agreement between G.D. Searle & Co. and Brigham Young University, with Daniel L. Simmons as its employee or agent, dated August 2, 2001, as amended on August 3, 2001, and the Confidentiality Agreement dated December 15, 2005.

TWENTY-FOURTH SPECIAL DEFENSE
(Failure to Mitigate)

As a twenty-fourth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' have a duty to mitigate their damages, and to the extent the evidence shows a failure on the part of Plaintiffs to do so, Defendants allege failure to mitigate damages as a defense.

TWENTY-FIFTH SPECIAL DEFENSE
(Failure to Patent)

As a twenty-fifth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to patent any technology at issue in this litigation.

TWENTY-SIXTH SPECIAL DEFENSE
(Independent Business and Legal Decision)

As a twenty-sixth and separate defense, and solely by the way of defense and not to be construed as an admission, Defendants allege that Plaintiffs and/or Plaintiffs' authorized representatives and designees voluntarily chose to forego the pursuit of any patent rights they now claim to have had on the basis of the Plaintiffs' own independent business judgment and independent legal advice without expecting or seeking, nor receiving or relying upon any business or legal advice from any Defendant.

TWENTY-SEVENTH SPECIAL DEFENSE
(No Ascertainable Loss)

As a twenty-seventh and separate defense, and solely by the way of defense and not to be construed as an admission, the claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

TWENTY-EIGHTH SPECIAL DEFENSE
(Comparative Negligence)

As a twenty-eighth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' claims are barred, in whole or in part, pursuant to the provisions of Utah Code Ann. § 78-27-38 *et. seq.*, to the extent of any fault of the Plaintiffs established by the evidence in the case.

TWENTY-NINTH SPECIAL DEFENSE
(Unnamed Parties)

As a twenty-ninth and separate defense, and solely by the way of defense and not to be construed as an admission, Plaintiffs' alleged claims and any alleged damages are barred, in whole or in part, to the extent the evidence shows that the same have been caused and/or proximately caused by the actions of third persons over whom Defendants have no control or for whom Defendants have no responsibility. To the extent the evidence shows that persons not named as parties to the action have caused or contributed to cause any of the alleged damages of Plaintiffs, Defendants reserve the right under Utah Code Ann. § 78-27-37 *et seq.* to have those persons' names included on any special verdict form and any fault attributable to them to be apportioned.

THIRTIETH SPECIAL DEFENSE
(Failure to State Claim for Punitive Damages)

As a thirtieth and separate defense, and solely by the way of defense and not to be construed as an admission, any claim of Plaintiffs for punitive damages is barred because no alleged act or omission of Defendants was done with reckless indifference or reckless disregard to any right of Plaintiffs.

THIRTY-FIRST SPECIAL DEFENSE
(Failure to State Claim for Punitive Damages)

As a thirty-first and separate defense, and solely by the way of defense and not to be construed as an admission, any claim of Plaintiffs for punitive damages is barred as a matter of law because there was no outrageous or malicious conduct by Defendants.

THIRTY-SECOND SPECIAL DEFENSE
(Failure to Meet the Statutory Requirements for Punitive Damages)

As a thirty-second and separate defense, and solely by the way of defense and not to be construed as an admission, Defendants allege that Plaintiffs' claim for punitive damages is subject to the provisions of Utah Code Ann. § 78-18-1 *et. seq.* and that such claims for punitive damages are barred by the one-year limitations period applicable to penalty statutes, as set forth in Utah Code Ann. § 78-12-29(2).

THIRTY-THIRD SPECIAL DEFENSE
(Additional Defenses)

As a thirty-third and separate defense, and solely by the way of defense and not to be construed as an admission, Defendants reserve the right to assert any additional defense which might come to their attention or might be developed during the pendency of this action.

PRAYER FOR RELIEF

WHEREFORE, Defendants Pfizer Inc., G.D. Searle LLC, and Pharmacia Corporation respectfully request that the Court enter a Judgment and Order:

1. Dismissing Plaintiffs' Complaint, and each and every claim for relief therein, with prejudice;
2. Awarding judgment in favor of Defendants on all counts of Plaintiffs' Complaint;
3. Declaring that Plaintiffs, either individually or collectively, have no right to recover for any of their asserted claims;
4. Declaring that Defendants, their officers, agents, servants, employees, all parent, subsidiary, and affiliate corporations or other business entities, and all other persons

acting in concert, participation, or privity with them, their successors, and assigns have not violated any of Plaintiffs' rights;

5. Declaring that Defendants have not damaged Plaintiffs, either individually or collectively, and that Plaintiffs are not entitled to an award of damages, interest, or costs in this case;

6. Declaring that Defendants have not willfully and deliberately committed fraud and that Plaintiffs are not entitled to punitive damages, attorneys fees, or expenses;

7. Declaring that Plaintiffs are not entitled to the relief requested or any other relief in this case;

8. Awarding Defendants their costs and expenses;

9. Awarding Defendants their reasonable attorneys' fees; and

10. Granting Defendants such other and further relief as the Court deems just and proper.

Dated: December 13, 2006

Respectfully submitted,

/s/ George M. Haley

George M. Haley, UT - 1302
David R. Parkinson, UT - 8268
HOLME ROBERTS & OWEN LLP
299 South Main Street, Suite 1800
Salt Lake City, UT 84111
Telephone: (801) 521-5800

Charles W. Douglas (*pro hac vice*)
Richard F. O'Malley, Jr. (*pro hac vice*)
Lisa A. Schneider (*pro hac vice*)
Neil H. Wyland (*pro hac vice*)
Todd L. Krause (*pro hac vice*)
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, IL 60603
Telephone: (312) 853-7000
Facsimile: (312) 853-7036

*Attorneys for Defendants Pfizer Inc., G.D.
Searle LLC, and Pharmacia Corporation*

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing document to be served by U.S. mail,
first class postage prepaid, upon:

David B. Thomas – UT 3228
Office of General Counsel
Brigham Young University
A-350 ASB
Provo, UT 84602
Telephone: (801) 422-4722
Facsimile: (801) 422-0265

Leo R. Beus (*pro hac vice*)
L. Richard Williams (*pro hac vice*)
Timothy J. Paris (*pro hac vice*)
Stephen M. Craig (*pro hac vice*)
Adam C. Anderson (*pro hac vice*)
Lee M. Adeline – UT 10830
BEUS GILBERT PLLC
4800 North Scottsdale Road, Suite 6000
Scottsdale, AZ 85251
Telephone: (480) 429-3000
Facsimile: (480) 429-3100

Attorneys for Plaintiffs

On this 13th day of December, 2006.

/s/ George M. Haley
Attorney for Defendants